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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,972

11/27/2006

Gert Worle

613-103

2883

23117 7590 10/07/2010
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EXAMINER

METZMAIER, DANIEL S

ART UNIT

PAPER NUMBER

1762

MAIL DATE

DELIVERY MODE

10/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,972	Applicant(s) WORLE ET AL.	
	Examiner Daniel S. Metzmaier	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/9/2010 & 2/2/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 15-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/2/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-32 are pending.

Election/Restrictions

1. Applicant's election with traverse of the restriction and election of Group I, claims 1-13, in the reply filed on 09 September 2010 is acknowledged. The traversal is on the ground(s) that Group III, claim 14, which depends on claim 1 is necessarily narrower than claim 1 since it includes all the limitations of claim 1. This is found persuasive because Group III, claim 14, sets forth all the elements of claim 1¹.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups II, IV, and V, there being no allowable generic or linking claim. Election is treated **without** traverse in the reply filed on 09 September 2010 since the only traversal relates to Group III, claim 14, which has been collapsed into Group I, claims 1-13. Claims 1-14 have been examined on the merits.

Priority

3. Receipt is acknowledged of papers received in this national stage application from the International Bureau (PCT Rule 17.2(a)), submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

¹ Claim 14 is deemed improper since the drying step renders the claim inconsistent with the preamble and the limitations in claim 1 directed to "measurable improvement" of specified properties. Claim 14 should be re-written as an independent claim.

Information Disclosure Statement

4. Landh et al, US 5,531,925, was considered and is of record as indicated in the PTO-892 form attached to the Office Action (Restriction) mailed 09 March 2010.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not properly identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

The Declaration only provides the filing date for priority document GB 0318244.1. The remaining priority documents are not properly identified.

Drawings

6. The drawings were received on 02 February 2006 are acceptable.

Specification

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. The disclosure is objected to because of the following informalities: the specification is objected under 37 CFR 1.77(b) and (c)

(b) The specification should include the following sections in order:

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- (1) Title of the invention, which may be accompanied by an introductory portion stating the name, citizenship, and residence of the applicant (unless included in the application data sheet).
 - (2) Cross-reference to related applications (unless included in the application data sheet).
 - (3) Statement regarding federally sponsored research or development.
 - (4) The names of the parties to a joint research agreement.
 - (5) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on a compact disc and an incorporation-by-reference of the material on the compact disc (see § 1.52(e)(5)). The total number of compact discs including duplicates and the files on each compact disc shall be specified.
 - (6) Background of the invention.
 - (7) Brief summary of the invention.
 - (8) Brief description of the several views of the drawing.
 - (9) Detailed description of the invention.
 - (10) A claim or claims.
 - (11) Abstract of the disclosure.
 - (12) "Sequence Listing," if on paper (see §§ 1.821 through 1.825).
- (c) The text of the specification sections defined in paragraphs (b)(1) through (b)(12) of this section, if applicable, should be preceded by a section heading in uppercase and without underlining or bold type.

9. The disclosure is objected to because of the following informalities: the specification should be reviewed and the reference to "FIGURE" should be changed to "FIG." to correspond with the labeling in the figures. See 37 CFR 1.84(u)(1).

Appropriate correction is required.

Claim Objections

10. Claims 1 and 4 are objected to because of the following informalities: The claims should be checked for spelling. Examples include "behaviour" should be changed to "behavior" in claim 1 and "stabilization" should be changed to "stabilization" in claim 4.

Appropriate correction is required.

Claim Interpretations

11. Claims 1-14 are directed to methods of forming dispersions and drying said dispersion. Claim 1 is representative as follows:

1. (Original) A method for forming a dispersion comprising non-lamellar amphiphile particles having improved phase behaviour, particle size distribution and/or storage stability, said method comprising
forming a dispersion of lamellar and optionally non-lamellar particles comprising at least one structuring agent in a polar solvent, heating said particles to an elevated temperature, followed by cooling,
wherein said heating is to a temperature and for a period sufficient to provide, after cooling, a measurable improvement in phase behaviour, particle size distribution and/or storage stability.

The limitations to “improved phase behaviour, particle size distribution and/or storage stability” and “measurable improvement in phase behaviour, particle size distribution and/or storage stability” have been considered and given little patentable weight since they are un-quantified.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1, 3-5, and 8-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morancais et al, US 5,670,099. Morancais et al (column 10, lines 20-34) discloses the process of claim 1, wherein:

In accordance with a particular embodiment of the present invention, a lamellar phase is prepared, by dissolving the lipid(s) in a solvent before forming the wall of the vesicles, evaporating the solvent under reduced pressure, then admixing the lipidic combination thus formed with the aqueous phase E, homogenizing and heating the mixture to a temperature of 10 °-150 ° C, preferably 40 ° -80 ° C, for 0.25 hours and returning the temperature to ambient temperature. **The cycle: homogenization-heating-return to ambient temperature is repeated at least once.** There is advantageously employed, as solvent, dichloromethane, chloroform, ethyl acetate, butyl acetate, ethyl formate, hexane, cyclohexane,

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toluene, petroleum ether, methanol, ethanol, propanol, methyl ether, ethyl ether and mixtures of at least two of them.

The equilibrium phases at higher temperatures and improved phase behavior, particle size distribution and/or storage stability would have been inherent since all the other elements of the process are clearly disclosed in the Morancais et al reference.

To the extent the Morancais et al reference differs from the claims in a lack of the non-lamellar phase, Morancais et al discloses the same process and would have been expected to form non-lamellar phases at the phase transition temperature, which would have been expected to vary based on the amphiphiles, polar solvent, further additives and concentrations thereof, which are known to affect the lamellar stability.

16. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (I), US 6482517, in view of Anderson (II), US PG PUB 2003/0232340.

Anderson (I) (example 10) discloses processes substantially as claimed.

Anderson (II) (paragraph [0057]) teaches:

“ . . . the present inventor described methods for producing dispersions of coated particles of a wide range of liquid crystalline phases including cubic and hexagonal. These methods include chemical reactions, heating-cooling temperature cycles . . . “,

when referencing 09/297,997 now Anderson (I), US 6482517.

Anderson (I) differs from the claims in the specific disclosure of the crystalline phases of the dispersions. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention to perform the Anderson (I) process for the advantages taught in Anderson (II) and the products contemplated therein. Merely modifying the process conditions such as temperature and concentration is not a

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patentable modification absent a showing of criticality for a result-effective variable, *i.e.*, a variable which achieves a recognized result.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (571) 272-1089. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David W. Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Daniel S. Metzmaier/
Primary Examiner, Art Unit 1762**

DSM